REMARKS

The final office action of November 8, 2005 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 22-25 and 28-35 remain in this case, claims 3-6, 8-11, 15-18, 22, and 26-27 being cancelled, claims 29-35 being added and claims 22-25 being amended by this response. No new matter has been added.

The language of claim 29 is supported by paragraph [0014], lines 3-4 of the published application.

The language of claim 30 is supported by paragraph [0018] of the published application.

The language of claim 31 is supported by claim 7 of the published application.

The language of claim 32 is supported by claim 10 of the published application.

The language of claim 33 is supported by paragraph [0014], lines 13-17 of the published application.

The language of claim 34 is supported by paragraph [0015], lines 1-3 of the published application.

The language of claim 35 is supported by [0019], lines 1-7 of the published application.

Objection to the Specification

The specification was objected to because the Examiner states that the Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention in claim 10. The Examiner further states that the Applicant is required to amend the specification to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element.

The Examiner quotes from MPEP 2181: "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112 first and second paragraphs, the PTO may still require the

applicant to amend the specification" (present office action, dated November 8, 2006, page 2, lines 9-12).

The first sentence of section 2181 of the MPEP states: "This section sets forth guidelines for the examination of 35 U.S.C. 112, sixth paragraph, 'means or step plus function' limitations in a claim" (emphasis added). The claims have been amended by the present response such that no means-plus-function language exists in the claims. Claim 10, as well as all of its dependent claims, has been cancelled by the present response. Therefore, it is respectfully suggested that the objection is overcome. Reconsideration and withdrawal of the objection to the specification is respectfully requested.

Objection to the Claims

Claims 3-6 and 8-11 were objected to because the Examiner states that Applicant has evoked sixth paragraph, means plus function language to define Applicant's invention.

The claims have been amended by the present response such that no means-plus-function language exists in the claims. Claims 3-6 and 8-11 have been cancelled by the present response. Therefore, it is respectfully suggested that the objection is overcome. Reconsideration and withdrawal of the objection is respectfully requested.

Rejection under 35 U.S.C. §112

Claims 3-6, 8-11, 15-18, and 21-28 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Applicant respectfully disagrees with this rejection.

Claims 3-6, 8-11, 15-18, 21, and 26-27 have been cancelled by the present response.

Regarding claims 22-25 and 28-35, the test for enablement is put forth in MPEP 2164.01. "Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the

enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)." (emphasis added).

As far as the Applicant knows, the present invention was the first to introduce individualized inhalation. A much more optimized inhalation of an aerosol is obtainable if the respiratory flow and the tidal volume (and the size of the particles) are individually selected for the specific patient. Such parameters are obtained, for example, by a physician or a health care institution and are in practice stored on a memory medium such as a smart card. The smart card is given to the patient who inserts the smart card, for example at home, into the inhalation device. The inhalation device then controls inhalation of the patient on the basis of these individual parameters. To help the Examiner understand the invention, in the last office action response dated August 26, 2005, the Applicant respectfully enclosed a brochure describing in detail the product AKITA that is based on the invention claimed in the present application. The inhalation with this system is described on page 6 of the brochure as follows:

"The AKITA can be individually adjusted for each patient on the basis of a lung function test. The patient's optimized breathing pattern is stored on a smart card, which, similar to a phone card, is slid into the AKITA device before the first inhalation. In this way, we at Inamed program an individual breathing pattern on the smart card for the respective medication and for the individual patient's lung function. This ensures an optimum treatment for every patient and every drug. The AKITA can even be set up so that the aerosol will be delivered to certain lung regions. If the lung function parameters or drug dosage change, we simply exchange the smart card."

Thus, with the inventive inhalation device, controlled inhalation is provided with high accuracy: the drug indeed reaches the target area in the lung. Such a controlled and targeted inhalation has not been achieved in the art prior to the applicant's invention.

Those skilled in the art would know that the adjustment of the respiratory flow and the tidal volume can be made, in practice, by valves or by controlling the air pump of the inhalator. Once a person skilled in the art understands the concept of inhalation on the basis of individual parameters (measured or obtained beforehand), the person skilled in the art would be able to put this concept into practice.

Regarding claims 22-25 and 28, the Examiner states that "[t]he means for adjusting and the adjustment mechanism claimed in the above claims has not been disclosed in such a way that one skilled in the art would have been able to make and use the device. It is unclear what structure would be capable of performing the claimed functions and exactly how it would interact or interconnect with the other explicitly claimed elements of the invention to arrive at the specified functions" (present office action, dated November 8, 2005, page 3, lines 12-16, emphasis added). Claim 25 is a method claim, and does not include an adjusting means of an adjusting mechanism. The Examiner further states that "[e]ven though claim 25 does not claim the means, clearly the adjusting steps require the adjusting means and therefore have been included in the rejections" (present office action, dated November 8, 2005, page 7, lines 8-9).

Amended claims 22-25 and claims 28-35 do not include any means or step plus function language. Therefore, the Applicant has not invoked 35 U.S.C. 112, sixth paragraph. It is respectfully submitted that MPEP 2181 is not applicable to the present claims and an enablement rejection of the claims on this basis is not proper.

Those skilled in the art know would be able to adjust individual aerosol doses administered by the inhalation device, because it is well known in the art that there are many ways to adjust respiratory flow and tidal volume (including valves or controlling the air pump of an inhalator).

Applicant believes that these amendments have fully addressed the Examiner's rejections, and the claims are now in condition for allowance. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 3-6, 8-11, 15-18, and 21-28 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner states that one skilled in the art would not be able to identify the structure which makes up the claimed adjusting means or adjustment mechanism, thus making the scope of the claim unclear and indefinite. Applicant respectfully disagrees with this rejection.

Claims 3-6, 8-11, 15-18, 21, and 26-27 have been cancelled by the present response.

Amended claims 22-25 and claims 28-35 do not include any means or step plus function language. Therefore, the Applicant has not invoked 35 U.S.C. 112, sixth paragraph. It is respectfully submitted that MPEP 2181 is not applicable to the present claims and an indefiniteness rejection of the claims on this basis is not proper.

Applicant believes that these amendments have fully addressed the Examiner's rejections, and the claims are now in condition for allowance. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. §102

Claims 3, 4, 8, 10, 11, 15, 18, 21, 22, and 25-28 were rejected under 35 U.S.C. 102(b) as being anticipated by Goodman (5,813,397). Applicant respectfully disagrees with the rejection.

Claims 3, 4, 8, 10, 11, 15, 18, 21, and 26-27 are cancelled by the present response.

Amended independent claim 25 claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising the steps of inputting into a device a plurality of individual patient parameters for the patient for the inhalation, comprising the substeps of inserting a memory medium into the device; and storing the individual patient parameters on the memory medium before the inhalation; and adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters, comprising the substeps of evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters".

Goodman discloses a method of delivering aerosolized medicine in response to appropriate points in the patient's detected breath flow. Goodman also discloses detecting changes in the patient's breath patterns as a basis for adjusting the amount of medication to be delivered. Goodman also discloses containing operating parameters for different medications in the device. Goodman also discloses "selecting certain processing subroutines, calibration coefficients, and operating parameters from a library of such information, or from an external source, for use by the main program to accommodate patient specific or drug specific requirements in different applications to treat predetermined medical conditions" (U.S. Patent No. 5,813,397, column 31, lines 3-8). Goodman does not disclose what "patient specific" requirements include.

Goodman only discloses storing medication parameters and adjusting administration based on breath patterns measured by the apparatus. Goodman does not disclose inserting a memory medium into the device or storing individual patient parameters on the memory medium before inhalation. Goodman also does not disclose adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Goodman does not disclose evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Goodman does not disclose each and every element of Applicant's claim 25. Therefore, it is respectfully suggested that the rejection of independent claim 25 as being anticipated by Goodman is overcome. Claims 22 and 28-35, being dependent upon and further limiting claim

25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Claims 5, 6, 9, 16, 17, 23 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman in view of Wallace (6,024,089).

Claims 5, 6, 9, 16, and 17 are cancelled by the present response.

Applicants respectfully disagree, and believe the claims, as amended, are patentable over Brown for the reasons given above in respect to the section 102 rejection of claim 25, from which claims 23 and 24 depend. The argument above as to the novelty of claim 25 is repeated here by reference.

Amended independent claim 25 claims, in part, a "method for administering a controlled inhalation of therapeutic aerosols ... comprising the steps of inputting into a device a plurality of individual patient parameters for the patient for the inhalation, comprising the substeps of inserting a memory medium into the device; and storing the individual patient parameters on the memory medium before the inhalation; and adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters, comprising the substeps of evaluating the individual patient parameters for the inhalation; and adjusting a respiratory flow or a tidal volume of the inhalation device based on the individual patient parameters".

Goodman teaches a method of delivering aerosolized medicine in response to appropriate points in the patient's detected breath flow. Goodman also teaches detecting changes in the patient's breath patterns as a basis for adjusting the amount of medication to be delivered. Goodman also teaches containing operating parameters for different medications in the device. Goodman also teaches "selecting certain processing subroutines, calibration coefficients, and operating parameters from a library of such information, or from an external source, for use by the main program to accommodate patient specific or drug specific requirements in different applications to treat predetermined medical conditions" (U.S. Patent No. 5,813,397, column 31, lines 3-8). Goodman does not teach or suggest what "patient specific" requirements include.

Goodman only teaches storing medication parameters and adjusting administration based on breath patterns measured by the apparatus. Goodman does not teach or suggest inserting a memory medium into a device or storing individual patient parameters on the memory medium before inhalation. Goodman also does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Goodman does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Wallace does not provide what Goodman lacks. Wallace teaches a ventilation control system for controlling the ventilation of a patient. Wallace teaches "a digital processor, a touch sensitive display screen and entry means cooperating to provide a user-friendly graphic interface for use in setting up and carrying out a wide variety of respiratory therapies" (U.S. Patent No. 6,024,089, column 2, lines 63-65). Wallace does not teach or suggest inserting a memory medium into a device or storing individual patient parameters on the memory medium before inhalation. Wallace also does not teach or suggest adjusting individual aerosol doses administered by the device on the basis of the individual patient parameters. In addition, Wallace does not teach or suggest evaluating the individual patient parameters for the inhalation and adjusting a respiratory flow or a tidal volume of the inhalation device based on individual patient parameters.

Goodman and Wallace, alone or in combination, do not teach or suggest all of the elements of claim 25. Therefore, it is respectfully submitted that claim 25 is not obvious over Goodman in view of Wallace. Claims 23-24 and 29-35, being dependent upon and further limiting claim 25, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with

Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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